K080752

SECTION 5 - 510(K) SUMMARY

MAY 14 2008

Submitter: Conceivex, Inc.
5 East Main Street
Saranac, MI 48881
616-642-0257

Contact: Michael LaVean

Date of Summary: March 14, 2008

Common Name: Polyurethane Condom
Trade Name: Conceivex Latex-free Semen Collector
Classification Name: Condom, Synthetic

A. Predicate Devices

The predicate devices are the Trojan Supra Polyurethane Condom, cleared under K050828, and the Conceivex Semen Collector cleared under K063227.

B. Device Description

The subject device is a polyurethane condom.

C. Intended Use

The Semen Collection Device is intended to be used as an accessory to the Oves Cervical Cap to collect semen for transfer to the cap prior to insertion in artificial insemination procedures.

D. Substantial Equivalence Summary

The Sagami Semen Collector is equivalent to the Sagami condom as it is the same condom made by the same manufacturer. The Sagami Semen Collector is also equivalent to the Avanti Semen Collection device. Both devices have the same intended use and indications for use, they are both made of polyurethane, and both have the same performance characteristics. Testing performed on the Sagami Condom demonstrates that with the new Indication for Use, it is as safe and as effective as the predicate device and thus, is substantially equivalent to it.

E. Technological Characteristics

The technological characteristics of the new device and the predicate device are identical.

F. Testing

A Human Sperm Survival Assay and a Mouse Embryo Assay performed on the Sagami non-latex condom demonstrated that the condom material has no deleterious effects on human semen or embryo development. The results of this testing demonstrate that the new devices is as safe and effective as the predicates.

G. Conclusion

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in: Section 513(i) of the FD&C Act, as Amended; 21 CFR Section 807, and; guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 14 2008

Conveivex, Inc.
% Mr. Blix Winston, MPA, MS
Submission Correspondent
ACMD Consulting, LLC
2600 Mullinix Mill Road
MT. AIRY MD 21771

Re: K080752
Trade/Device Name: Conceivex Latex-free Semen Collector
Regulation Number: 21 CFR 884.5250
Regulation Name: Cervical cap
Regulatory Class: II
Product Code: OBB
Dated: March 14, 2008
Received: April 22, 2008

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K080752

Device Name: **Conceivex Latex-free Semen Collector**

Indications for Use:

The Sagami Polyurethane Semen Collection Device is intended to be used as an accessory to the Oves Cervical Cap to collect semen for transfer to the cap prior to insertion in artificial insemination procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080752